**Practitioner's Docket No.** 1438-15 **PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Patent application
of _____
Inventor(s)
for _____
Title of Invention
_____
the specification of which is being transmitted herewith

OR

In re application of: BHATTACHARYA, Sampad; et al.
Application No.: 10/ 563,631
Filed: 01-06-2006
For: EXTENDED RELEASE OSMO-MICROSEALED FORMULATION
Group No.:
Examiner:

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

# INFORMATION DISCLOSURE STATEMENT

**CERTIFICATION UNDER 37 C.F.R. §§ 1.8(a) and 1.10***
*(When using Express Mail, the Express Mail label number is mandatory; Express Mail certification is optional.)*

I hereby certify that, on the date shown below, this correspondence is being:

**MAILING**

☒ deposited with the United States Postal Service in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

**37 C.F.R. § 1.8(a)**

☒ with sufficient postage as first class mail.

**37 C.F.R. § 1.10***

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**TRANSMISSION**

☐ facsimile transmitted to the Patent and Trademark Office, (703) _____

Date: 4-13-06

Signature

John S. Egbert
*(type or print name of person certifying)*

** Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.*

NOTE: *"An information disclosure statement shall be considered by the Office if filed by the applicant within any one of the following time periods:*

*(1) Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);*

*(2) Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;*

*(3) Before the mailing date of a first Office action on the merits; or*

*(4) Before the mailing date of a first Office action after the filing of a request for continued examination under § 1.114."*

*37 C.F.R. § 1.97(b).*

NOTE: *"Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. § 1.56(a).*

*"Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and*

*(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or*

*(2) It refutes, or is inconsistent with, a position the applicant takes in:*

*(i) Opposing an argument of unpatentability relied on by the Office, or*

*(ii) Asserting an argument of patentability.*

*"A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability." 37 C.F.R. § 1.56(b)*

*"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:*

*(1) each inventor named in the application;*

*(2) each attorney or agent who prepares or prosecutes the application; and*

*(3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. § 1.56(c).*

NOTE: *The "duty as described in § 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O.G. 13 -25 at 17.*

***WARNING:*** *"No information disclosure statement may be filed in a provisional application." 37 C.F.R. § 1.51(d).*

## List of Sections Forming Part of This Information Disclosure Statement

The following sections are being submitted for this Information Disclosure Statement:

*(check sections forming a part of this statement: discard unused sections and number pages consecutively)*

1. ☒ Preliminary Statements
2. ☒ FORMS PTO/SB/08A and 08B (formerly FORM PTO-1449)
3. ☐ Statement as to Information Not Found in Patents or Publications
4. ☐ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
5. ☐ Cumulative Patents or Publications

6. ☒ Copies of Listed Information Items Accompanying This Statement
7. ☐ Concise Explanation of Non-English Language Listed Information Items
   7A. ☐ EPO Search Report
   7B. ☐ English Language Version of EPO Search Report
8. ☐ Translation(s) of Non-English Language Documents
9. ☒ Concise Explanation of English Language Listed Information Items (Optional)
10. ☒ Identification of Person(s) Making This Information Disclosure Statement

*(complete the following, if appropriate)*

Sections , respectively, have been continued on ADDED PAGE(S).

*NOTE: "Once the minimum requirements are met, the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).*

## Section 1. Preliminary statements

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. § 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability (37 C.F.R. § 1.97(h)), or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

Please type a plus sign (+) inside this box → [+]

PTO/SB/08A (10-96)
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Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449A/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

*(use as many sheets as necessary)*

Sheet 1 of 1

| *Complete if Known* | |
|---|---|
| **Application Number** | 10/563,631 |
| **Filing Date** | 01-06-2006 |
| **First Named Inventor** | BHATTACHARYA, Sampad |
| Group Art Unit | |
| Examiner Name | |
| Attorney Docket Number | 1438-15 |

## U.S. PATENT DOCUMENTS

| Examiner Initials* | Cite No.[1] | U.S. Patent Document Number | Kind Code[2] (*if known*) | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|---|---|---|---|---|---|---|
| | | 6,274,171 | | Sherman, et al. | 08-14-2001 | |
| | | 6,403,120 | | Sherman, et al. | 06-11-2002 | |
| | | 6,419,958 | | Sherman, et al. | 07-16-2002 | |
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## FOREIGN PATENT DOCUMENTS

| Examiner Initials* | Cite No.[1] | Foreign Patent Document Office[3] | Number[4] | Kind Code[5] (*if known*) | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T[6] |
|---|---|---|---|---|---|---|---|---|
| | | WO | 03/041692 | | SELA YORAM | 05-22-2003 | | |
| | | WO | 01/51041 | | FAOUR JOAQUINA | 07-19-2001 | | |
| | | WO | 98/47491 | | ODIDI ISA; ODIDI AMINA | 10-29-1998 | | |
| | | WO | 03/055475 | | KERC JANEZ; et al. | 07-10-2003 | | |
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| Examiner Signature | | Date Considered | |
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number. [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

## Section 6. Copies of Listed Information Items Accompanying This Statement

*NOTE: 37 C.F.R. § 1.98(a)(2) requires that any information disclosure statement filed under § 1.97 shall include: "A legible copy of:*

*(i) Each U.S. patent application publication and U.S. and foreign patent;*

*(ii) Each publication or that portion which caused it to be listed;*

*(iii) For each cited pending U.S. application, the application specification including the claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion; and*

*(iv) All other information or that portion which caused it to be listed; . . . "*

Legible copies of all items listed in Forms PTO/SB/08A and 08B (formerly Form PTO-1449) accompany this information statement.

*(complete the following, if applicable)*

☐ Exception(s) to above:

- ☐ Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.
- ☐ Cumulative patents or publications identified in Section 5.

**Section 9. Concise Explanation of English Language Listed Information Items (OPTIONAL)**

*NOTE: "Applicants may, if they wish, provide a concise explanation of why English-language information is being submitted and how it is understood to be relevant. Concise explanations are helpful to the Office, particularly where documents are lengthy and complex and applicant is aware of a section that is highly relevant to patentability or where a large number of documents are submitted and applicant is aware that one or more are highly relevant to patentability." Notice of April 20, 1992 (1138 O.G. 37-41, 38). See also § 609, M.P.E.P., 8th Edition.*

US patent 6,274,171, issued on August 14, 2001 to Sherman, et al., discloses a 24 hour extended release dosage formulation and unit dosage form thereof of venlafaxine hydrochloride, an antidepressant, which provides better control of blood plasma levels than conventional tablet formulations which must be administered two or more times a day and further provides a lower incidence of nausea and vomiting than the conventional tablets. More particularly, the invention comprises an extended release formulation of venlafaxine hydrochloride comprising a therapeutically effective amount of venlafaxine hydrochloride in spheroids comprised of venlafaxine hydrochloride, microcrystalline cellulose and, optionally, hydroxypropylmethylcellulose coated with a mixture of ethyl cellulose and hydroxypropylmethylcellulose.

US patent 6,403,120, issued on June 11, 2002 to Sherman, et al., discloses a 24 hour extended release dosage formulation and unit dosage form thereof of venlafaxine hydrochloride, an antidepressant, which provides better control of blood plasma levels than conventional tablet formulations which must be administered two or more times a day and fiber provides a lower incidence of nausea and vomiting than the conventional tablets. More particularly, the invention comprises an extended release formulation of venlafaxine hydrochloride comprising a therapeutically effective amount of venlafaxine hydrochloride in spheroids comprised of

venlafaxine hydrochloride, microcrystalline cellulose and, optionally, hydroxypropylmethylcellulose coated with a mixture of ethyl cellulose and hydroxypropylmethylcellulose.

US patent 6,419,958, issued on July 16, 2002 to Sherman, et al., discloses a an extended release once-a-daily pharmaceutical composition consisting of hard gelatin capsules filled with film coated spheroids comprising a therapeutically effective amount of Venlafaxine Hydrochloride, microcrystalline cellulose and, optionally, Hydroxypropyl methylcellulose extruded and spheronized and the formed spheroids further coated with a mixture of ethyl cellulose and Hydroxypropyl methylcellulose. Venlafaxine has been formulated into a controlled release dosage form with the ability to provide in a single dose a therapeutic blood serum level of the drug over a twenty four hour period. By this method, tighter plasma therapeutic range control can be obtained and a multiple dosing is avoided in this manner. The sharp peaks and troughs in blood plasma drug levels are avoided as well.

WO 03 / 041692 discloses an alternative approach of preparing extended release spheroids of Venlafaxine. Venlafaxine Hydrochloride is coated on a non pareil inert core, which is further coated with an inert polymer layer and subsequently with a third coat of an polymeric layer which enables the controlled release.

WO 01/51041 teaches a formulation comprising a tablet and a semi-permeable membrane surrounding the core tablet. The core comprises Venlafaxine and one osmotic agent. The semipermeable membrane surrounding the core has a passageway drilled through it either mechanically or by laser. The coated osmotic drug delivery system based tablet is further coated with an external coat comprising a therapeutically effective amount of an anti-psychotic agent.

WO 98 / 47491 teaches a novel controlled release composition and the system has been named intelliGITransportersTM. The composition can be formulated as an tablet or an suppository and optionally coated with an anionic polymer for enteric effect. The said coat is proposed to prevent the initial burst effect and impart the gastrointestinal tract (GIT) stealth characteristics especially in the presence of food. Prior to coating the core tablet is prepared by mixing a blend of two polymers with opposite wetting characteristics and have a water contact angle theta such that cos of theta is between +0.9848 and -0.9848. Though Venlafaxine is a part of its exhaustive list of the drugs where the proposed technology could be applicable, it does not appear in any of the example.

WO 03 / 055475 teaches a composition for once a day administration using hydrogel technology. It describes a process for the preparation of a solid controlled release pharmaceutical formulation comprising the steps of dissolving Venlafaxine and polyvinyl pyrrolidone in an aqueous solvent, applying the resulting solution onto low viscosity hydrophilic polymer, homogeneously mixing the obtained granulate with a high viscosity hydrophilic polymer, and compressing the granulate to obtain a core which is then coated with a polymeric coating comprising a water high permeable polymer and a water low permeable polymer.

## Section 10. Identification of Person(s) Making This Information Disclosure Statement

The person making this statement is

*(check each applicable item)*

(a) ☐ the inventor(s) who signs below

SIGNATURE OF INVENTOR

*(type name of inventor who is signing)*

(b) ☐ an individual associated with the filing and prosecution of this application (37 C.F.R. § 1.56(c))

SIGNATURE OF INVENTOR

*(type name of inventor who is signing)*

(c) ☐ the practitioner who signs below on the basis of the information:

*(check each applicable item)*

☐ supplied by the inventor(s).

☐ supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. § 1.56(c))

☐ in the practitioner's file.

SIGNATURE OF PRACTITIONER

Reg. No.: 30,627

Tel. No.: (713) 224-8080

Customer No.: 24106

John S. Egbert
*(type or print name of practitioner)*

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